IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: **Jackson, Robertson, Kenche, Thompson, Prabaharan, Anderson, Abbott, Goncalves, Nesbitt, Shoenwaelder, and Saylik**

Title: **Inhibition Of Phosphoinositide 3-Kinase Beta**

Patent No.: **7,598,377**	Issued **October 6, 2009**
Serial No.: **10/522,777**	Group Art Unit: **1625**
National Stage Filing Commenced: **January 31, 2005**	Examiner: **Bernard I. Dentz**
35 U.S.C. § 371(c) Date: **July 6, 2006**	Confirmation No.: **1694**
	Filed by EFS Web on: **October 30, 2009**

Mail Stop Petition
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

REQUEST FOR CORRECTION OF PATENT TERM ADJUSTMENT
UNDER 37 C.F.R. § 1.705(d)

Patentee hereby requests reconsideration of the Patent Term Adjustment (PTA) accorded the above-referenced patent. Reconsideration of the final PTA calculation to increase total PTA from 92 to 674 days, is respectfully requested.

Remarks

(1) Measuring Overlap of "A Delay" and "B Delay"

"A Delays" are defined as delays by the U.S. Patent and Trademark Office (PTO) under 35 U.S.C. § 154(b)(1)(A), which guarantees prompt PTO response. "B Delays" are defined as delays by the PTO under 35 U.S.C. § 154(b)(1)(B), which guarantees no more than three year application pendency. To the extent that the periods of delay overlap, the period of any term adjustment shall not exceed the actual number of days the issuance of the patent was delayed. 35

U.S.C. § 154(b)(2)(A). As outlined in *Wyeth et al. v. Jon W. Dudas* (U.S. District Court, D.C., CA No. 07-1492, Mem. Op. September 30, 2008), the only way that these periods of time can "overlap" is if they occur on the same day. If an "A delay" occurs on one calendar day and a "B delay" occurs on another calendar day, they do not overlap and 35 U.S.C. § 154(b)(2)(A) does not limit the extension to one day. Id.

The PTA for the instant patent, as currently calculated and shown on the face of the patent, apparently relies on the premise that the application was delayed under 35 U.S.C. § 154(b)(1)(B) *before* the initial three-year period expired. The *Wyeth v. Dudas* court determined that this construction cannot be squared with the language of 35 U.S.C. § 154(b)(1)(B), which applies "if the issue of an original patent is delayed due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years." "B delay" begins only after the PTO has failed to issue a patent within three years, not before. Id.

(2) Measuring "B Delay" for a National Stage Filing under 35 U.S.C. § 371

In addition to and independent of the "overlap" issue addressed above, Patentee respectfully submits that the Office did not apply the proper standard for determining the period of "B Delay" under 35 U.S.C. § 154(b)(1)(B). It is Patentee's understanding that for purposes of calculating "B Delay," the Office measured application pendency as beginning on July 6, 2006, the date on which the application fulfilled the requirements of 35 U.S.C. § 371. However, as detailed below, the Office has admitted that using the filing date under 35 U.S.C. § 371(c) is incorrect and that the relevant statutes and regulations require that when calculating "B Delay" for a national stage filing under 35 U.S.C. § 371, application pendency must be measured from the date that the national phase filing commences under 35 U.S.C. § 371(b) or (f) (i.e., not from the date on which the application fulfilled the requirements of 35 U.S.C. § 371).

On October 6, 2009, the Office published a notice in the Official Gazzette (1347 OG 49) acknowledging that the computer program that the Office uses to calculate PTA based upon a national phase filing under 35 U.S.C. § 371 contains an error. The notice states

> The USPTO's computer program incorrectly calculates the three-year pendency provision of 35 U.S.C. § 154(b)(1)(B) in international applications as being measured from the date that the requirements of 35 U.S.C. § 371 were fulfilled rather than the date

the national stage commenced under 35 U.S.C. § 371(b) or (f) in
the international application.

Id. The PTA for the above-referenced patent was calculated using the date that
the requirements of 35 U.S.C. § 371 were fulfilled rather than the date the
national stage was commenced under 35 U.S.C. § 371 (b) or (f).

The above referenced patent commenced the national phase under 35
U.S.C. § 371 (b) or (f) on January 31, 2005.

REVIEW OF PATENT TERM ADJUSTMENT CALCULATION

"A Delay"

A first PTO action was due on or before September 6, 2007 (the date that
is fourteen months after July 6, 2006, the date on which the application fulfilled
the requirements of 35 U.S.C. § 371). The PTO mailed the first action (a
restriction requirement) on November 5, 2007, thereby according a PTO Delay of
60 days. Patentee does not dispute the PTO's calculation for this "A Delay" from
September 7, 2007 (the day after the date that is fourteen months after the date on
which the application fulfilled the requirements 35 U.S.C. § 371), to November 5,
2007. See 37 C.F.R. §§ 1.702(a)(1) and 1.703(a)(1).

In view of the period of "A Delay" detailed above, the total "A Delay" for
this patent should be calculated as 60 days.

"B Delay"

The present application is a national stage filing under 35 U.S.C. § 371 of
international application number PCT/IB03/04177, filed August 18, 2003. The
national stage for the present application "commenced" under the provisions of
35 U.S.C. § 371 on January 31, 2005.

The period beginning on February 1, 2008 (the day after the date that is
three years after January 31, 2005, the date that the national stage commenced),
and ending October 6, 2009 (the date the above-referenced patent was issued), is
614 days in length.

In view of the period of "B Delay" detailed above, the total "B Delay" for this patent should be calculated as 614 days. The PTO calculated 32 days of delay for issuance of a patent more than three years after filing. Patentee respectfully submits that the PTO's calculation of this "B Delay" is incorrect and that the correct PTO Delay for issuance beyond three years from filing is 614 days. See 37 C.F.R. §§ 1.702(b) and 1.703(b).

Overlap of "A Delay" and "B Delay"

As detailed above, "A Delay" accumulated during the following period:

September 7, 2007 to November 5, 2007.

As detailed above, "B Delay" accumulated during the following period:

February 1, 2008 to October 6, 2009.

The "A Delay" and the "B Delay" did not overlap (See, *Wyeth*).

Applicant Delay

There were no circumstances constituting a failure to engage in reasonable efforts to conclude processing or examination of the application as set forth 37 C.F.R. § 1.704.

Terminal Disclaimer

This patent is not subject to a terminal disclaimer.

Conclusion

In consideration of the events described above, Patentee believes the PTA calculation of 92 days is incorrect. As such, Patentee respectfully requests reconsideration of the PTA in the following manner:

1) Total PTO Delay should be calculated as 674 days (i.e., the sum of 60 days of "A Delay" and 614 days of "B Delay" minus the 0 days of overlap);

2) Total Applicant Delay should be calculated as 0 days; and

3) Total PTA should be calculated as 674 days.

The Commissioner is hereby authorized to debit any fee due or credit any overpayment to deposit account 50-0436.

Respectfully submitted,

/Daniel M. Scolnick, Reg.# 52201/
Daniel M. Scolnick, Ph.D.
Registration No. 52,201.

Date: **October 30, 2009**

Pepper Hamilton LLP
400 Berwyn Park
899 Cassatt Road
Berwyn, PA 19312-1183

Telephone: 610.640.7820
Facsimile: 610.640.7835

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: **Jackson, Robertson, Kenche, Thompson, Prabaharan, Anderson, Abbott, Goncalves, Nesbitt, Shoenwaelder, and Saylik**

Title: **Inhibition Of Phosphoinositide 3-Kinase Beta**

Patent No.: **7,598,377**	Issued **October 6, 2009**
Serial No.: **10/522,777**	Group Art Unit: **1625**
National Stage Filing Commenced: **January 31, 2005**	Examiner: **Bernard I. Dentz**
35 U.S.C. § 371(c) Date: **July 6, 2006**	Confirmation No.: **1694**
	Filed by EFS Web on: **October 30, 2009**

Mail Stop Petition
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

REQUEST FOR CORRECTION OF PATENT TERM ADJUSTMENT
UNDER 37 C.F.R. § 1.705(d)

Patentee hereby requests reconsideration of the Patent Term Adjustment (PTA) accorded the above-referenced patent. Reconsideration of the final PTA calculation to increase total PTA from 92 to 674 days, is respectfully requested.

Remarks

(1) Measuring Overlap of "A Delay" and "B Delay"

"A Delays" are defined as delays by the U.S. Patent and Trademark Office (PTO) under 35 U.S.C. § 154(b)(1)(A), which guarantees prompt PTO response. "B Delays" are defined as delays by the PTO under 35 U.S.C. § 154(b)(1)(B), which guarantees no more than three year application pendency. To the extent that the periods of delay overlap, the period of any term adjustment shall not exceed the actual number of days the issuance of the patent was delayed. 35

U.S.C. § 154(b)(2)(A). As outlined in *Wyeth et al. v. Jon W. Dudas* (U.S. District Court, D.C., CA No. 07-1492, Mem. Op. September 30, 2008), the only way that these periods of time can "overlap" is if they occur on the same day. If an "A delay" occurs on one calendar day and a "B delay" occurs on another calendar day, they do not overlap and 35 U.S.C. § 154(b)(2)(A) does not limit the extension to one day. Id.

The PTA for the instant patent, as currently calculated and shown on the face of the patent, apparently relies on the premise that the application was delayed under 35 U.S.C. § 154(b)(1)(B) *before* the initial three-year period expired. The *Wyeth v. Dudas* court determined that this construction cannot be squared with the language of 35 U.S.C. § 154(b)(1)(B), which applies "if the issue of an original patent is delayed due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years." "B delay" begins only after the PTO has failed to issue a patent within three years, not before. Id.

(2) Measuring "B Delay" for a National Stage Filing under 35 U.S.C. § 371

In addition to and independent of the "overlap" issue addressed above, Patentee respectfully submits that the Office did not apply the proper standard for determining the period of "B Delay" under 35 U.S.C. § 154(b)(1)(B). It is Patentee's understanding that for purposes of calculating "B Delay," the Office measured application pendency as beginning on July 6, 2006, the date on which the application fulfilled the requirements of 35 U.S.C. § 371. However, as detailed below, the Office has admitted that using the filing date under 35 U.S.C. § 371(c) is incorrect and that the relevant statutes and regulations require that when calculating "B Delay" for a national stage filing under 35 U.S.C. § 371, application pendency must be measured from the date that the national phase filing commences under 35 U.S.C. § 371(b) or (f) (i.e., not from the date on which the application fulfilled the requirements of 35 U.S.C. § 371).

On October 6, 2009, the Office published a notice in the Official Gazzette (1347 OG 49) acknowledging that the computer program that the Office uses to calculate PTA based upon a national phase filing under 35 U.S.C. § 371 contains an error. The notice states

> The USPTO's computer program incorrectly calculates the three-
> year pendency provision of 35 U.S.C. § 154(b)(1)(B) in
> international applications as being measured from the date that the
> requirements of 35 U.S.C. § 371 were fulfilled rather than the date

the national stage commenced under 35 U.S.C. § 371(b) or (f) in the international application.

Id. The PTA for the above-referenced patent was calculated using the date that the requirements of 35 U.S.C. § 371 were fulfilled rather than the date the national stage was commenced under 35 U.S.C. § 371 (b) or (f).

The above referenced patent commenced the national phase under 35 U.S.C. § 371 (b) or (f) on January 31, 2005.

REVIEW OF PATENT TERM ADJUSTMENT CALCULATION
"A Delay"

A first PTO action was due on or before September 6, 2007 (the date that is fourteen months after July 6, 2006, the date on which the application fulfilled the requirements of 35 U.S.C. § 371). The PTO mailed the first action (a restriction requirement) on November 5, 2007, thereby according a PTO Delay of 60 days. Patentee does not dispute the PTO's calculation for this "A Delay" from September 7, 2007 (the day after the date that is fourteen months after the date on which the application fulfilled the requirements 35 U.S.C. § 371), to November 5, 2007. See 37 C.F.R. §§ 1.702(a)(1) and 1.703(a)(1).

In view of the period of "A Delay" detailed above, the total "A Delay" for this patent should be calculated as 60 days.

"B Delay"

The present application is a national stage filing under 35 U.S.C. § 371 of international application number PCT/IB03/04177, filed August 18, 2003. The national stage for the present application "commenced" under the provisions of 35 U.S.C. § 371 on January 31, 2005.

The period beginning on February 1, 2008 (the day after the date that is three years after January 31, 2005, the date that the national stage commenced), and ending October 6, 2009 (the date the above-referenced patent was issued), is 614 days in length.

In view of the period of "B Delay" detailed above, the total "B Delay" for this patent should be calculated as 614 days. The PTO calculated 32 days of delay for issuance of a patent more than three years after filing. Patentee respectfully submits that the PTO's calculation of this "B Delay" is incorrect and that the correct PTO Delay for issuance beyond three years from filing is 614 days. See 37 C.F.R. §§ 1.702(b) and 1.703(b).

Overlap of "A Delay" and "B Delay"

As detailed above, "A Delay" accumulated during the following period:

September 7, 2007 to November 5, 2007.

As detailed above, "B Delay" accumulated during the following period:

February 1, 2008 to October 6, 2009.

The "A Delay" and the "B Delay" did not overlap (See, *Wyeth*).

Applicant Delay

There were no circumstances constituting a failure to engage in reasonable efforts to conclude processing or examination of the application as set forth 37 C.F.R. § 1.704.

Terminal Disclaimer

This patent is not subject to a terminal disclaimer.

<u>Conclusion</u>

In consideration of the events described above, Patentee believes the PTA calculation of 92 days is incorrect. As such, Patentee respectfully requests reconsideration of the PTA in the following manner:

I) Total PTO Delay should be calculated as 674 days (i.e., the sum of 60 days of "A Delay" and 614 days of "B Delay" minus the 0 days of overlap);

2) Total Applicant Delay should be calculated as 0 days; and

3) <u>Total PTA should be calculated as 674 days.</u>

The Commissioner is hereby authorized to debit any fee due or credit any overpayment to deposit account 50-0436.

Respectfully submitted,

/Daniel M. Scolnick, Reg.# 52201/
Daniel M. Scolnick, Ph.D.
Registration No. 52,201.

Date: **October 30, 2009**

Pepper Hamilton LLP
400 Berwyn Park
899 Cassatt Road
Berwyn, PA 19312-1183

Telephone: 610.640.7820
Facsimile: 610.640.7835

10/522,777	INHIBITION OF PHOSPHOINOSITIDE3-KINASE BETA	10-21-2009::19:00:57

Patent Term Adjustments

Patent Term Adjustment (PTA) for Application Number: 10/522,777

Filing or 371(c) Date:	07-06-2006	USPTO Delay (PTO) Delay (days):	92
Issue Date of Patent:	10-06-2009	Three Years:	-
Pre-Issue Petitions (days):	+0	Applicant Delay (APPL) Delay (days):	0
Post-Issue Petitions (days):	+0	Total PTA (days):	92
USPTO Adjustment(days):	+0	Explanation Of Calculations	

Patent Term Adjustment History

Date	Contents Description	PTO(Days)	APPL(Days)
09-16-2009	PTA 36 Months	32	
10-06-2009	Patent Issue Date Used in PTA Calculation		
09-09-2009	Dispatch to FDC	↑	
09-03-2009	Application Is Considered Ready for Issue	↑	
08-28-2009	Issue Fee Payment Verified	↑	
08-28-2009	Statement Filed Indicating a Loss of Entitlement to Small Entity Status	↑	
08-28-2009	Issue Fee Payment Received	↑	
07-13-2009	TC Return to Pubs	↑	
07-10-2009	Filing Receipt - Corrected	↑	
06-16-2009	Pubs Case Remand to TC	↑	
06-01-2009	Mail Notice of Allowance	↑	
05-28-2009	Document Verification	↑	
05-28-2009	Notice of Allowance Data Verification Completed	↑	
05-22-2009	Examiner's Amendment Communication	↑	
05-21-2009	Paralegal TD Accepted	↑	
12-18-2008	Terminal Disclaimer Filed	↑	
03-24-2009	Date Forwarded to Examiner	↑	
03-17-2009	Response after Non-Final Action	↑	
02-17-2009	Mail Miscellaneous Communication to Applicant	↑	
02-13-2009	Miscellaneous Action with SSP	↑	
12-19-2008	Date Forwarded to Examiner	↑	
12-18-2008	Response after Non-Final Action	↑	
09-23-2008	Mail Non-Final Rejection	↑	
09-19-2008	Non-Final Rejection	↑	
07-18-2008	Date Forwarded to Examiner	↑	
06-17-2008	Response after Non-Final Action	↑	
04-23-2008	Change in Power of Attorney (May Include Associate POA)	↑	
04-22-2008	Correspondence Address Change	↑	
03-18-2008	Mail Non-Final Rejection	↑	
03-11-2008	Non-Final Rejection	↑	

Date	Event	
01-10-2008	Date Forwarded to Examiner	✦
12-21-2007	Response to Election / Restriction Filed	✦
12-21-2007	Request for Extension of Time - Granted	✦
11-05-2007	Mail Restriction Requirement	60
11-02-2007	Requirement for Restriction / Election	✦
05-10-2007	Case Docketed to Examiner in GAU	✦
09-08-2006	IFW TSS Processing by Tech Center Complete	✦
08-30-2006	Cleared by OIPE CSR	✦
08-29-2006	Cleared by OIPE CSR	✦
08-29-2006	Cleared by OIPE CSR	✦
08-29-2006	Cleared by OIPE CSR	✦
08-29-2006	Cleared by OIPE CSR	✦
08-29-2006	Cleared by OIPE CSR	✦
08-29-2006	Cleared by OIPE CSR	✦
07-06-2006	371 Completion Date	✦
08-18-2006	Application Dispatched from OIPE	
07-06-2006	Additional Application Filing Fees	
07-06-2006	A statement by one or more inventors satisfying the requirement under 35 USC 115, Oath of the Applic	
07-25-2006	Mail-Petition Decision - Granted	
07-06-2006	Petition Entered	

Close Window